K063630

ATTACHMENT 7 510(k) SUMMARY

510(k) Summary

General Information

Classification	Class II
Trade Name	AtriCure Ablation System
Manufacturer	AtriCure, Inc. 6033 Schumacher Park Drive West Chester, OH 45069
Contact	Elsa Abruzzo Vice President, Clinical and Regulatory Affairs

JAN 26 2007

Intended Use

The AtriCure Ablation System is intended to ablate soft tissues during general surgery using radiofrequency energy.

Predicate Devices

The predicate devices for the AtriCure Ablation System are the AtriCure Bipolar System (K020919), the AtriCure Transpolar™ System (K052893), and the Medtronic Cardioablate Surgical Ablation System (K060400)

Device Description

The AtriCure Ablation System includes a hand held, single use, bipolar radiofrequency (RF) surgical instrument (Isolator® Transpolar Clamps or Isolator Synergy™ Clamps) intended for the ablation of soft tissues and an accessory instrument guide (Glidepath™ Tape). The clamp handpieces are connected via an integral cable to the AtriCure re-useable Ablation and Sensing Unit (ASU2) or an Isolator Switch Matrix (ASB3) console.

Materials

All materials in the AtriCure Ablation System are suitable for their intended use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The AtriCure Ablation System is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Regulatory Technology Services, LLC
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K063630
Trade/Device Name: Atricure Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 4, 2006
Received: December 6, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063630

Device Name: AtriCure Ablation System

Indications For Use:

The AtriCure Ablation System is intended to ablate soft tissues during general surgery using radiofrequency energy.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ision Sign-Off)
ivision of General, Restorative
and Neurological Devices

(k) Number K063630